Fix my Abstract!

Title: (word count = 21)

The utility of Exparel® for improving pain control in a multimodal, opioid-sparing approach after TKA: a single-center, prospective, single-blind cohort study

Background: (word count = 171)

Liposomal bupivacaine (Exparel®) is a long-acting local anesthetic preparation with demonstrated efficacy over placebo in reducing post-operative pain and opioid requirements in hemorrhoidectomy and bunionectomy. Limited economic data suggests an improvement in length of stay (LOS) and hospitalization costs with a multi-modal analgesic regimen including liposomal bupivacaine compared to an opioid-based analgesic regimen employing intravenous (IV) patient-controlled analgesia (PCA) after colorectal surgery. A dose-ranging pharmacokinetic study of liposomal bupivacaine in total knee replacement (TKA) did not find significant differences in pain scores through 72 hours post-operatively for currently-approved doses as compared to conventional bupivacaine.

Efficacy and cost-effectiveness of liposomal bupivacaine local infiltration around the surgical site in TKA has not been assessed in a multi-modal, opioid-sparing analgesic approach as is used at the Grant Medical Center Bone and Joint Center. Given lack of clinical evidence over standard of care paired with significant medication safety concerns and economic impact, liposomal bupivacaine was previously denied formulary status at OhioHealth. This study is designed to address current gaps in comparative efficacy and economic data.

Methods: (word count = 246)

This is a prospective, randomized, single-blinded, controlled trial comparing liposomal bupivacaine local infiltration around the surgical site to our current intra-operative analgesic approach. This study was approved by our institutional IRB. All adult unilateral TKA patients of the collaborating surgeon were eligible to participate in the study. Patients were excluded if they were non-English speaking, unable to give informed consent, admitted from or discharged to a medical facility, unable to complete a 140-foot walk at baseline, have contraindications to either study drug or to nerve blockade, or taking scheduled long-acting opioid medications before their surgery. Patients were randomized in a 1:1 open-label fashion to receive either local infiltration with liposomal bupivacaine or popliteal nerve block with ropivacaine and peri-articular injection per current protocol. All patients were to receive a pre-operative adductor canal nerve block from Anesthesia and a post-operative opioid-sparing analgesic regimen per institutional protocol. Patients and all post-operative healthcare providers were blinded to study arm assignment.

The primary outcome measure is the number of physical therapy (PT) sessions necessary to achieve first successful community walk (140 feet). Secondary outcomes measures include total opioid consumption in oral morphine equivalents (OMEs) during admission, average visual analogue pain scores (VAPs) during admission, length of stay, incidence of opioid-related adverse drug events (ORADEs) during admission, PT personnel time spent during admission, time spent in operating room (OR), time spent in post-anesthesia care unit (PACU), total drug charges for admission, total hospitalization charges for admission, and readmission within 30 days.

Results: (word count = 102)

A total of 60 patients were enrolled per our a priori power calculation. The final analysis included 59 patients after 1 exclusion for randomization error. No significant demographic differences between the study arms were found. There was no statistically significant difference in the primary outcome of number of physical therapy (PT) sessions required to achieve home-going discharge goals (3.0 ± 1.2 vs 3.6 ± 1.3, P=0.137), nor in the clinical secondary outcomes. We pursued additional secondary outcomes analyses to assess economic impact of the compared modalities. A significant difference in medication charges was found, calling into question the cost-benefit of this agent.

Conclusions: (word count = 59)

We found no significant difference in any clinical endpoint studied, but economic analyses revealed increased medication costs. These results are especially pertinent in the era of bundled payment reimbursement approaches for TKA. Our study supports earlier literature suggesting no significant clinical benefit of using liposomal bupivacaine over standard of care in TKA and underscores cost-of-care concerns with this agent.

Total Word Count = 598